Cahoy Supp. Dec. Ex. 98

August 15, 2022

Intuitive Surgical, Inc.
Kunal Gunjal
Sr. Regulatory Affairs Specialist
1266 Kifer Road, Building 101
Sunnyvale, California 94086

Re: K214095
Trade/Device Name: da Vinci X/Xi (IS4200/IS4000) 8mm Reusable Instruments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: July 21, 2022
Received: July 22, 2022

Dear Kunal Gunjal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2022.08.15 08:26:50 -04'00'

Mark Trumbore
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214095

Device Name
da Vinci Xi/X (IS4000/IS4200) 8mm Reusable Instruments

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model IS4000) and the Intuitive Surgical Endoscopic Instrument Control System (da Vinci X Surgical System, Model IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (K214095)

510(k) Owner	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact	Kunal Gunjal Sr. Regulatory Affairs Specialist Phone Number: 408-523-8017 Email: Kunal.Gunjal@intusurg.com
Date	12th August 2022
Trade Name	*da Vinci Xi/X* (IS4000/IS4200) 8mm Reusable Instruments
Common Name	Endoscope and accessories
Classification	Class II, 21 CFR 876.1500
Product Codes	NAY, GCJ
Review Panel	General and Plastic Surgery
Predicate Devices	K203632 (*da Vinci X/Xi 8mm Reusable* Instruments)

Device Description:

The *da Vinci X/Xi* (IS4200/IS4000) 8mm *EndoWrist* Instruments have a unique articulating design at their distal tips that mimics the human wrist. While seated at the Surgeon Console of the Surgical System, the surgeon can precisely control movements of the end effectors/instrument tips to perform one or more specific surgical tasks e.g., grasping, suturing, cutting, cauterizing, or tissue manipulation.

Indications for Use:

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System, Model IS4000) and the Intuitive Surgical Endoscopic Instrument Control System (*da Vinci X* Surgical System, Model IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Table 1 includes a comparison between the subject devices and predicate devices.

Table 1: Comparison of Predicate and Subject Devices (*da Vinci X/Xi EndoWrist 8mm* Instruments)

Characteristic	Predicate Device *da Vinci X/Xi (IS4200/IS4000) EndoWrist (8mm)* Instruments (K203632)	Subject Device *da Vinci X/Xi (IS4200/IS4000) EndoWrist (8mm)* Instruments (K214095)

Number of Lives and Reprocessing Cycles

da Vinci X/Xi 8mm Reusable Instruments	Predicate Device Model Number	Predicate Device Number of Lives	Predicate Device Number of Reprocessing Cycles	*da Vinci X/Xi 8mm Reusable Instruments*	Subject Device Model Number	Subject Device Number of Lives	Subject Device Number of Reprocessing Cycles
8mm Maryland Bipolar Forceps	470172	10	15	8mm Maryland Bipolar Forceps	471172	14	19
8mm Fenestrated Bipolar Forceps	470205	10	15	8mm Fenestrated Bipolar Forceps	471205	14	19
8mm Force Bipolar	470405	10	15	8mm Force Bipolar	471405	12	17
8mm Large Needle Driver	470006	10	15	8mm Large Needle Driver	471006	15	20
8mm Mega SutureCut Needle Driver	470309	10	15	8mm Mega SutureCut Needle Driver	471309	15	20
8mm Cadiere Forceps	470049	10	15	8mm Cadiere Forceps	471049	18	23
8mm ProGrasp Forceps	470093	10	15	8mm ProGrasp Forceps	471093	18	23
8mm Micro Bipolar Forceps	470171	10	15	8mm Micro Bipolar Forceps	471171	14	19
8mm Curved Bipolar Dissector	470344	10	15	8mm Curved Bipolar Dissector	471344	14	19
8mm Long Bipolar Grasper	470400	10	15	8mm Long Bipolar Grasper	471400	14	19
8mm Large SutureCut Needle Driver	470296	10	15	8mm Large SutureCut Needle Driver	471296	15	20
8mm Long Tip Forceps	470048	10	15	8mm Long Tip Forceps	471048	18	23
8mm Cobra Graspers	470190	10	15	8mm Cobra Graspers	471190	18	23

Technological Characteristics:

There are changes to the *da Vinci X/Xi* 8mm Reusable Instruments labeling, with increased number of lives (uses) and reprocessing cycles. The impacted Product Part numbers and the number of lives (uses) and reprocessing cycles for the subject devices are listed in **Table 1**.

Performance Data:

Performance test data demonstrates that the subject device is substantially equivalent to the predicate device. The testing conducted consisted of Cleaning Validation, Reliability/Life Testing, Electrical Performance Testing and Thermal Effects Testing.

- **Cleaning Validation**: Cleaning Validation was performed to validate the efficacy of the manual and automated cleaning process in accordance with the following standards and guidance documents:

  - FDA Guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"*, document issued on: March 17, 2015 (Amended on June 9, 2017).
  - AAMI TIR 12:2020 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
  - AAMI TIR 30: 2011/(R)2016, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
  - ANSI/AAMI ST15883-1:2009/(R) 2014, Washer-disinfectors: General requirements, terms and definitions and tests

  The *da Vinci X/Xi* 8mm Reusable Instruments successfully met the acceptance criteria for all markers. The test results demonstrate that the *da Vinci X/Xi* 8mm Reusable Instruments can be cleaned using the following cleaning methods:

  - Automated cleaning process using a compatible automated washer/disinfector.
  - Manual cleaning process using an ultrasonic bath.

- **Reliability/Life Testing**: Reliability/Life Testing was performed to ensure that *da Vinci X/Xi* 8mm Reusable Instruments are not adversely affected by the increased number of lives (uses) and reprocessing cycles for these subject devices as listed in **Table 1**.

- **Electrical Performance Testing**: Electrical Performance Testing was performed after subjecting the representative subject devices/instruments (which have *"active components/accessories"*) to multiple reuse and reprocessing cycles (including both manual and automated cleaning process). This testing was performed to ensure the *da Vinci X/Xi* 8mm Extended Lives Instruments family (subject devices as listed in **Table 1**) meet the requirements within the *FDA guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, Document Issued on March 9, 2020.*

- **Thermal Effects testing:** Thermal Effects testing was performed to confirm that thermal effects on tissue are comparable between the subject and predicate devices. The testing was performed in accordance with the requirements within the *FDA guidance, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", Document Issued on March 9, 2020.*

Conclusion:

Based on the intended use, indications for use, technological characteristics and performance data, the subject device is substantially equivalent to the proposed predicate device.